NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-cv-3770 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion of Plaintiff Eli Lilly ("Plaintiff"). Plaintiff asks this Court to reconsider a portion of its Opinion of December 31, 2009, wherein the Court denied Defendants' motion for summary judgment of non-enablement. In the alternative, Plaintiff requests that the Court certify its Opinion for interlocutory appeal.

For the reasons stated below, Plaintiff's motion is **denied**.

I. BACKGROUND

The facts surrounding this matter are recited more fully in the Court's Opinion in Eli Lilly & Co. v. Actavis Elizabeth LLC, 2009 U.S. Dist. LEXIS 121063 (D.N.J. Dec. 31, 2009) ("Op."). Here, the Court will provide only the facts related to its holding regarding enablement.

A. Procedural History

Plaintiff brought this action for patent infringement against Defendants Actavis Elizabeth LLC, Apotex Inc., Aurobindo, Sun Pharmaceuticals, Teva Pharmaceuticals, Sandoz Inc., and Mylan Pharmaceuticals Inc. ("Defendants"). Plaintiff asserted U.S. Patent No. 5,658,590 ("the '590 Patent"), a method-of-use patent which covers methods of treating attention deficit/hyperactivity disorder ("ADHD") with tomoxetine (also referred to as atomoxetine). Claim 1 of the patent is illustrative, it covers: A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine.

On May 13, 2009, Defendants moved for summary judgment, asking the Court to find that the '590 Patent specification did not establish utility, rendering the patent invalid for lack of enablement under 35 U.S.C. § 112. Defendants argued that the specification failed to establish utility because: (1) the patent applicants did not submit test results at the time of the filing to show that atomoxetine could be used to treat ADHD; and (2) a person of ordinary skill in the art at the time of filing would not have recognized the claimed method's utility from reading the specification of the '590 Patent. Plaintiff responded that (1) post-filing date tests results confirm the utility of the invention, and (2) a person of ordinary skill in the art would have recognized the utility of the '590 Patent in view of the specification. On December 31, 2009, this Court denied Defendants' motion for summary judgment.

B. Product Development and Patent Prosecution

Before filing the '590 Patent application on January 11, 1995, Plaintiff began to work with Dr. Joseph Biederman and Massachusetts General Hospital ("MGH") to conduct a double-blind, placebo-controlled clinical trial on the use of atomoxetine to treat ADHD (the "Lilly/MGH study").

Preparations for the first clinical trial to test atomoxetine for the treatment of ADHD began before the filing date of the '590 Patent application, although the first patient to take atomoxetine in connection with the trial did so after the '590 Patent application was filed in January 1995. Plaintiff had gathered the results of this trial by May 1995, when MGH sent Dr. Heiligenstein, the patent's co-inventor, a report of the study. Plaintiff later performed phase II and III clinical trials, successfully using atomoxetine to treat ADHD patients, and resulting in FDA approval.

The '590 Patent did not disclose any test data indicating that atomoxetine was useful in treating ADHD. Plaintiff and Dr. Heiligenstein, however, had human clinical data supporting and confirming the asserted utility of the patent in May 1995, approximately five months after the '590 Patent application was filed in January 1995 (and prior to issuance of the patent). This data was not submitted to the PTO during prosecution.

II. STANDARD OF REVIEW

Motions for reconsideration are governed by L. Civ. R. 7.1(i). See U.S. v. Compaction Sys. Corp., 88 F. Supp. 2d 339, 345 (D.N.J. 1999). A motion pursuant to Local Rule 7.1(i) may be granted if (1) an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice. Database Am., Inc. v. Bellsouth Adver. & Pub. Corp., 825 F. Supp. 1216, 1220 (D.N.J. 1993). Such relief is "an extraordinary remedy" that is to be granted "very sparingly." See NL Indus. Inc. v. Commercial Union Ins. Co., 935 F. Supp. 513, 516 (D.N.J. 1996). Local Rule 7.1(i) does not contemplate a recapitulation of arguments considered by the Court before rendering its original decision. See Bermingham v. Sony Corp. Of Am., Inc., 820 F. Supp. 834, 856 (D.N.J. 1992), aff'd, 37 F.3d 1485 (3d Cir. 1994). In other words, a motion for reconsideration is not an

appeal. It is improper on a motion for reconsideration to "ask the court to rethink what it ha[s] already thought through." Oritani Sav. & Loan Ass'n v. Fidelity & Deposit Co., 744 F. Supp. 1311, 1314 (D.N.J. 1990).

III. PLAINTIFF'S MOTION FOR RECONSIDERATION

Plaintiff requests reconsideration of certain findings of this Court with respect to its enablement decision, wherein the Court denied Defendants' motion for summary judgment of invalidity for lack of enablement. Specifically, Plaintiff argues that the Court improperly held that: (A) test results obtained after the '590 patent application's filing date, but before the patent issued, cannot be relied upon to substantiate the specification's assertion of utility, and (B) evidence substantiating the specification's assertion of utility cannot be considered by this Court unless such evidence had previously been provided to the PTO during prosecution of the '590 "atent. The Court will address these contentions in turn.

A. Post-Filing Date Test Results & Establishing Utility

Plaintiff's first argument in support of reconsideration is that the Court improperly held that "test results obtained after the '590 patent application's filing date but before the patent issued cannot be relied upon to substantiate the specification's assertion of utility." If that was in fact this Court's holding, then perhaps reconsideration would be appropriate–Plaintiff, however, has mischaracterized this Court's determination.

This Court held that "test results, here . . . cannot **establish** utility because they were not available at the time of the patent application's filing date." Op. at 21, 28 (emphasis added). That is, the Court determined that post-filing date test results, alone, can not suffice to establish utility at the time of filing (which is the point at which utility must be established). See, e.g., Janssen

Pharmaceutica N.V. v. Teva Pharms. USA, Inc., 583 F.3d 1317, 1325 (Fed. Cir. 2009) (finding that test results "were not available at the time of the application, and the district court properly held that they could not be used to **establish** enablement.") (emphasis added); Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1322-24 (Fed. Cir 2005); In re Brana, 51 F.3d 1560, 1566-67 (Fed. Cir. 1995) (noting that post-filing test results could confirm the assertion of utility that was already established through *in vivo* test results referenced in the patent specification). In re Jolles, 628 F.2d 1322 (C.C.P.A. 1980) (finding that four declarations containing pre-filing test results were sufficient to establish utility). But, as the Federal Circuit has explained, post-filing evidence "does not render an insufficient disclosure enabling, but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility)." Brana, at 1567 n.19.

This Court did not suggest that post-filing date test results could not properly be used to support an assertion of utility when such utility was in doubt. Here, however, there was essentially no initial disclosure of utility to bolster with additional evidence. Plaintiff argued that post-filing date test results alone could establish utility; the Court disagreed, and determined that Plaintiff's test results could not establish utility.

The Court, as explained in its original summary judgment Opinion, relied heavily upon the Federal Circuit's recent decision in Janssen. Janssen is the most recent pronouncement of the Federal Circuit with respect to establishing utility, and this Court believes that it ruled in accordance with this binding precedent.

B. Establishing Utility with Evidence Not Before the PTO During Patent Prosecution

Plaintiff's second argument is that the Court improperly held that "evidence substantiating the specification's assertion of utility cannot be considered unless such evidence had previously been

provided to the PTO during prosecution of the '590 patent." The Court's holding, however, was not so broad. The Court found that, here, "even if the [test] results were available prior to the application date as required, they still would not be sufficient to establish utility as they were not provided to the examiner." In other words, in this case, because data evidencing the patent's utility was not provided to the PTO, data that subsequently became available could not remedy the patent's deficiency in failing to disclose utility. This Court's holding, then, was more narrow than as described by Plaintiff.

The Court agrees with Plaintiff that a patentee is "not precluded from offering evidence in support of patentability that was not submitted during prosecution." See Knoll Pharm. Co. v. Teva Pharmaceuticals USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("There is no requirement that . . . the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence in response to litigation attack[; n]or is it improper to conduct additional experiments and provide later-obtained data in support of patent validity."); TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc., 336 F.3d 1322, 1330 (Fed. Cir. 2003) (noting that, in litigation, a patentee is not limited to presenting only those arguments in support of patentability that were made before PTO). This argument, however, is inapplicable to the facts of this case. This Court was required to consider whether the applicant **established** a credible utility at the time of filing–not whether evidence not provided to the PTO could ever be used to rebut a challenge to patentability.

Here, the Court considered whether the utility of the '590 Patent was properly established at the time of the patent's filing. Accordingly, post-filing date test results would be unable to satisfy this requirement. Again, then, the question is not whether such data may **substantiate** utility, but

rather whether the data can **establish** utility in the first instance. This Court found that it cannot.

For the reasons stated above, Plaintiff's motion for reconsideration is denied.

IV. PLAINTIFF'S REQUEST FOR CERTIFICATION

Alternatively, Plaintiff requests that this Court certify its Opinion for interlocutory appeal pursuant to Section 1292(b). The Court does not find certification to be appropriate here.

A. Applicable Law

Pursuant to 28 U.S.C. § 1292(b), a district court may certify for immediate appeal an otherwise non-appealable order, if it is satisfied "that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." The statute imposes three requirements before certification may be granted. The order to be certified must (1) involve a controlling question of law; (2) offer substantial ground for difference of opinion; and (3) have the potential to materially advance the ultimate termination of the litigation, if appealed immediately. See Katz v. Carte Blanche Corp., 496 F.2d 747, 754 (3d Cir. 1974); P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp., 161 F. Supp.2d 355, 358 (D.N.J. 2001).

Certification is entirely within the district court's discretion even if the three criteria are met; indeed, courts have acknowledged that "certification is appropriate only in exceptional cases." Piazza v. Major League Baseball, 836 F. Supp. 269, 270 (E.D. Pa. 1993) (internal quotations and citations omitted); see also Bachowski v. Usery, 545 F.2d 363, 368 (3d Cir. 1976).

B. Analysis

The Court will consider the three requirements for certification in turn. First, an issue of law is "controlling" if its incorrect disposition would require reversal of the final judgment. See Katz

v. Carte Blanche Corp., 496 F.2d 747, 755 (3d Cir. 1974). Here, the issue of law in dispute is whether post-filing date test results, alone, may establish a patent's utility. This is a controlling issue of law, as Plaintiff asserts that it can produce test results clearly demonstrating the '590 Patent's utility.

Although the disputed issue concerns a controlling issue of law, certification is still inappropriate in this case because Plaintiff cannot establish the second and third requirements for certification.

Plaintiff has failed to show that there is a substantial ground for difference of opinion by demonstrating that "other courts have substantially differed in applying that standard." Harter v. GAF Corp., 150 F.R.D. 502, 518 (D.N.J. 1993). A substantial ground for difference of opinion exists when there is a genuine doubt or conflicting precedent as to the correct legal standard. Bradburn Parent Teacher Store, Inc. v. 3M, 2005 U.S. Dist. LEXIS 15815, at *4 (E.D. Pa. Aug. 2, 2005). As explained above, and in its December 31, 2009 Opinion, this Court has determined that post-filing test results cannot be relied upon to **establish** a patent's utility at the time of filing–although such results could **substantiate** an assertion of utility in the patent. See Section III.A, supra. Plaintiff has not cited a case that this Court reads to hold otherwise.

Plaintiff similarly cannot meet the third requirement for certification. A party seeking certification must show that an immediate appeal "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). The purpose of section 1292(b) is "to permit decision of legal issues as to which there is considerable question without requiring the parties first to participate in a trial that may be unnecessary. . . ." Johnson v. Alldredge, 488 F.2d 820, 823 (3d Cir. 1973), cert. denied, Cronrath v. Johnson, 419 U.S. 882 (1974). Typically, § 1292(b) is applied in situations

where, if the trial court decision were reversed on appeal, the litigation would then end. See, e.g., Katz v. Carte Blanche Corp., 496 F.2d 747, 750 (3d Cir. 1974), cert. denied, 419 U.S. 885 (1974); Gorso v. Bell Equip. Corp., 476 F.2d 1216 (3d Cir. 1973). That is not the case here. There are a number of outstanding issues relevant to the enforceablity of the '590 Patent patentability, such as obviousness and inequitable conduct. If this Court's enablement holding was modified on appeal (in the manner urged by Plaintiff), a trial on the remaining issues would still have to be held. This would potentially lead to piecemeal appeals, without advancing the litigation. Accordingly, certification is inappropriate in this case.

V. CONCLUSION

Plaintiff's motion for reconsideration is **denied**, and the Court will not certify its December 31, 2009 Opinion for appeal.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: February 23, 2010
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Mark Falk, U.S.M.J.
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